

**REMARKS/ARGUMENTS**

Claims 1-11 are currently pending in the instant application. Claim 1 is amended as set forth in detail below. No new matter is added. Applicants reserve the right to pursue claims of original scope in a related, co-pending application. In view of the amendments and remarks set forth herein, reconsideration of all pending claims is respectfully requested.

**Rejections under 35 U.S.C. § 112, first paragraph**

Claims 1-11 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification as filed. The Examiner continues to allege that the claims are not enabled because of a "failure to provide guidance on the administration of xenogeneic cells or allogeneic cells." (Office Action dated 12/01/2005 at page 3, first full paragraph.)

With respect to administration of xenogeneic cells, while Applicants disagree with the Examiner for at least the reasons of record, but to further expedite prosecution of the present application, claim 1 has been amended to recite a "method for increasing the proliferation of non-xenogeneic thymocytes in a non-human animal." Support for this amendment is found in the application at, for example, page 17, line 19 to page 18, line 5. In view of this amendment, the claims explicitly exclude embodiments comprising xenogeneic transplant of thymocytes.

Regarding administration of allogeneic cells, the Examiner states that "the specification does not disclose that the thymocyte or isolated multipotent cell are types for MHC mismatches prior to administration." (Office Action dated 12/01/2005 at page 4.) In response, Applicants note that, according to the MPEP, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public." MPEP § 2164.05(a) (emphasis provided). Accordingly, claims "are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for non-inclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art." (*Id.* at 2164.08.) Here, because HLA haplotype matching was well-known in the art as of the effective filing date, and indeed was considered routine in the context of tissue allografts, non-recitation of such a limitation does not render the claims non-enabled.

In view of the amendments and remarks set forth above, Applicants believe the present claims to be enabled by the specification as filed under 35 U.S.C. § 112, first paragraph. Withdrawal of the rejection is respectfully requested.

### **Rejections under 35 U.S.C. § 102**

Claims 1-11 remain rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Roberts *et al.* (U.S. 5,958,769). The Examiner contends that by "monitoring the increase in nucleated cells in the thymus, Roberts *et al.* is literally detecting an increase in thymocytes, and is thus detecting an increase in thymocyte proliferation as encompassed by the amended claims." This rejection is overcome in part and traversed in part as set forth below.

For a reference to anticipate a claim under 35 U.S.C. § 102, the reference must expressly or inherently disclose each and every limitation recited in the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, the reference must disclose the "identical invention ... in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In this case, because other nucleated cell types in addition to "thymocytes" are present in the thymus, Roberts' disclosure of an increase in nucleated cells in the thymus is not equivalent to detecting an increase in thymocytes, since the Roberts studies did not determine whether the observed increase in nucleated cells was the result of an increase in cells positively identified as thymocytes or an increase in other nucleated cell types present in the thymus. Further, Roberts did not determine whether the increase in cells was due to an increase in proliferation or a decrease in cell death. (*See, e.g.*, specification at page 32, lines 29 and 30, noting that "[t]hymocyte number is a function of the balance between cell proliferation and cell death.") Thus, Roberts does not disclose the invention as claimed because Roberts does not specifically identify the increased nucleated cells as an increase in "proliferation" of "thymocytes."

While Applicants do not agree with the rejection for at least the reasons above, but in order to further expedite prosecution of this application, independent claim 1 is amended

to recite that monitoring of the animal for thymocyte proliferation comprises "obtaining from the animal a sample of hematopoietic cells and positively identifying a subpopulation thereof as thymocytes." Support for this amendment is found in the application at, *e.g.*, page 31, line 29 to page 32, line 27. Because Roberts does not disclose the positive identification of thymocytes, this amendment further distinguishes the claims from Roberts.

In view of the amendments and remarks above, Applicants believe claims 1-11 to be patentable over Roberts *et al.* under 35 U.S.C. § 102(e). Withdrawal of the rejection is respectfully requested.

### CONCLUSION

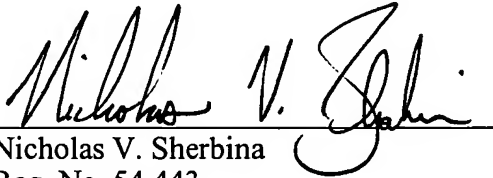
In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Date: June 1, 2006

By:

  
Nicholas V. Sherbina  
Reg. No. 54,443

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 206-467-9600  
Fax: 415-576-0300  
NVS:seh/jms  
60763377 v1